**NIAMS SMALL GRANT PROGRAM FOR NEW INVESTIGATORS**

**RELEASE DATE:** October 2, 2003

**PA NUMBER:** PAR-04-002

**EXPIRATION DATE:** October 24, 2005

Department of Health and Human Services (DHHS)

**PARTICIPATING ORGANIZATIONS:**

National Institutes of Health (NIH)
(http://www.nih.gov)

**COMPONENTS OR PARTICIPATING ORGANIZATIONS:**

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
(http://www.niams.nih.gov)

**APPLICATION RECEIPT DATES:** February 24, 2004, June 24, 2004, October 22, 2004, February 24, 2005, June 24, 2005, October 24, 2005

**CATALOGUE OF FEDERAL DOMESTIC ASSISTANCE NUMBER (S)** 93.846

**THIS PA CONTAINS THE FOLLOWING INFORMATION**



**PURPOSE OF THIS PA**

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) is seeking small grant (R03) applications to stimulate and facilitate the entry of promising new investigators into areas of research of interest to the NIAMS. This solicitation will

provide support for pilot research that is likely to lead to a subsequent individual research project grant (R01).

## RESEARCH OBJECTIVES

The NIAMS Small Grant program is designed to facilitate the entry of promising new investigators into research on arthritis and musculoskeletal and skin diseases and injuries. Brief summaries of the focuses of the NIAMS' Extramural Program branches are listed below. For more detailed information about scientific areas of interest to the NIAMS, applicants are encouraged to refer to the NIAMS website at http://www.niams.nih.gov.

## SUMMARY

o Rheumatic Diseases

The mission of the Rheumatic Diseases Branch is to promote and support research leading to prevention, diagnosis and cure of rheumatic and related diseases. The Branch supports basic, epidemiologic, and clinical research on etiology, pathogenesis, course, interventions, and outcomes in rheumatic and related diseases.

o Muscle Biology

The Muscle Biology Branch encourages and supports research on skeletal muscle, its diseases and disorders, and its central role in human physiology and exercise. Topics include the molecular structure of muscle and the molecular mechanisms that produce force and motion. One focus of this program is understanding the alterations in muscle resulting from increased exercise regimens and, conversely, the atrophy that follows immobilization during injury or illness.

o Musculoskeletal Diseases

This Branch supports studies of the skeleton including bones, joints and associated connective tissues. Broad areas of interest include skeletal development, metabolism, mechanical properties, and responses to injury. Clinical and basic research in the areas of osteoporosis and orthopaedic sciences are of particular interest under this program. Other musculoskeletal disorders of interest include osteoarthritis, osteogenesis imperfecta, and Paget's disease. The Program supports research in the area of acute and chronic injuries of the musculoskeletal system including work related and repetitive stress injuries. Research proposals related to the development of new technologies with the potential to improve treatment and/or diagnosis of skeletal disorders and to facilitate the repair of trauma in the normal skeleton are of great interest. In addition, bioengineering, sports medicine and musculoskeletal fitness are areas of special research emphasis.

o Skin Diseases

This Branch supports basic and clinical studies of the skin in normal and disease states. The wide range of skin diseases under study with NIAMS support includes keratinizing disorders such as psoriasis and ichthyosis, atopic dermatitis and other chronic inflammatory skin disorders, the vesiculobullous diseases such as epidermolysis bullosa and pemphigus, acne, and vitiligo.

**MECHANISM OF SUPPORT**

This PA will use the National Institutes of Health (NIH) Small Grant (R03) Award mechanism. As an applicant, you will be solely responsible for planning, directing, and executing the proposed project. The total project period for an application submitted in response to this PA may not exceed three years. Applicants may request up to $50,000 (direct costs) per year.This PA uses just-in-time concepts. It also uses the modular budget format. (see http://grants.nih.gov/grants/funding/modular/modular.htm).

**FUNDS AVAILABLE**

It is anticipated that, for FY 2004 and FY 2005, approximately $1.5 million (total costs) will be available for the first year of support for this initiative. It is anticipated that up to 15 to 20 new grants will be awarded each fiscal year under this program. Awards are contingent on the availability of appropriated funds and on the receipt of sufficiently meritorious applications meeting the stated eligibility requirements.

**ELIGIBLE INSTITUTIONS**

You may submit (an) application(s) if your institution has any of the following characteristics:

o For-profit or non-profit organizations
o Public or private institutions, such as universities, colleges, hospitals, and laboratories
o Units of State and local governments
o Eligible agencies of the Federal government
o Foreign institutions are not eligible to apply
o Faith-based or community-based organizations

**INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS**

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support.

o Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators. Applications are especially encouraged from new investigators who hold a faculty position at an HBCU (Historically Black

College or University) or other institutions that have student populations consisting predominantly of individuals from racial or ethnic groups that are underrepresented in science and by investigators at minority serving institutions.

o Grants awarded through this PA may not be used to support thesis or dissertation research.

o Former and current recipients of Academic Research Enhancement Awards (AREA) (R15), Mentored Clinical Scientist Development Awards (K08), Mentored Research Scientist Development Awards (K01), Mentored Patient Oriented Research Career Development Award (K23), Shannon Awards (R55), or Individual (F32) or Institutional (T32) National Research Service Award (NRSA) training support are eligible to apply for this Small Grant Program, dependent upon the status of other support for the project. Any current support by the F32 or T32 mechanisms must terminate before Small Grant support begins.

o Individuals whose sole previous support has been through pilot and feasibility studies (with the exception of R21 support from NIAMS) may apply.

o Current and previous recipients of NIH funding through Research Project Grants (R01), FIRST (R29) awards or any non-mentored career development award mechanism are ineligible for this Small Grants Program.

o The NIAMS will not award a new R03 grant if the project period of the new grant would overlap with the project period of a previously awarded NIAMS R03 grant. In addition, the NIAMS will not accept an R03 application from a principal investigator who has held two previous NIAMS R03s.

o Principal Investigators of research subprojects of Research Program Projects (P01) and Centers (P50 and P60) and individuals who have received research support in arthritis, musculoskeletal, or skin research from the National Science Foundation (NSF) or Department of Veterans Affairs (VA) as Principal Investigators are also ineligible.

Investigators who have questions about eligibility should contact one of the program officials listed under Inquiries.

**WHERE TO SEND INQUIRIES**

We encourage your inquiries concerning this PA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

o Direct your questions about scientific/research issues to:

Alan N.Moshell, M.D.
Skin Diseases Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
One Democracy Plaza
6701 Democracy Blvd., Suite 800, Bethesda, MD 20892-4872
Telephone: (301) 594-5017
FAX: (301) 480-4543
Email: alan_n_moshell@nih.gov

o Direct your questions about peer review issues to:

Glen Nuckolls, Ph.D.
Review Branch National Institute of Arthritis and Musculoskeletal and Skin Diseases
One Democracy Plaza
6701 Democracy Blvd, Suite 800
Bethesda, MD 20892-4872
Telephone: 301-594-4974
Fax: 301-402-2406
Email: nuckollg@mail.nih.gov

o Direct your questions about financial or grants management matters to:

Melinda Nelson
Grants Management Officer National Institute of Arthritis and Musculoskeletal and Skin Diseases One Democracy Plaza
6701 Democracy Blvd. Suite 800
Bethesda, MD 20892-4872
Telephone: (301) 594-3535
FAX: (301) 480-5450
Email: nelsonm@mail.nih.gov

**SUBMITTING AN APPLICATION**

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). Applications must have a Dun and Bradstreet (D&S) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling (866) 705-5711 or through the web site at http://www.dunandbradstreet.com . The DUNS number should be entered on line 11 of the face page of the PHS 398 form. The PHS 398 available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

**SUPPLEMENTARY INSTRUCTIONS**

The Research Plan is limited to 10 pages.

The title, "NIAMS Small Grant Program for New Investigators," and number of the program announcement (PAR-04-002) must be typed on line 2 of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed photocopies in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040, MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application and all copies of the appendix material must be sent to:

Glen Nuckolls, Ph.D.
Review Branch National Institute of Arthritis and Musculoskeletal and Skin Diseases
One Democracy Plaza
6701 Democracy Blvd, Suite 800
Bethesda, MD 20892-4872
Telephone: 301-594-4974
Fax: 301-402-2406
Email: nuckollg@mail.nih.gov

Applications received after any of the receipt dates listed above will be deferred to the next review cycle. A Principal Investigator may submit only one R03 application to the NIAMS in any review cycle. Applicants may not submit another research application for the same review cycle in which an R03 is submitted, if that application involves significant scientific overlap with the R03 application.

**APPLICATION RECEIPT DATES:** February 24, 2004, June 24, 2004, October 22, 2004, February 25, 2004, June 24, 2005, October 24, 2005

**SPECIFIC INSTRUCTIONS FOR MODULAR BUDGET GRANT APPLICATIONS:** Applications requesting up to $250,000 per year in direct costs must be submitted in a modular budget grant format. The modular budget grant format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in $25,000 modules. Section C of the research grant application instructions for the PHS 398 (re 5/2001) at

http://grants.nih.gov/grants/funding/phs398/phs398.html includes step-by-step guidance for preparing modular grants. Additional information on modular grants is available at http://grants.nih.gov/grants/funding/modular/modular.htm.

**APPLICATION PROCESSING:** Applications must be received on or before the receipt dates listed on the first page. The CSR will not accept any application in response to this PAR that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an unfunded version of an application already reviewed, but such applications bust in an Introduction addressing the previous critique.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within 8 weeks.

**PEER REVIEW PROCESS**

Applications submitted for this PAR will be assigned to NIAMS. Appropriate scientific review groups convened by NIAMS in accordance with the standard NIH peer review procedures (http://www.csr.nih.gov/refrev.htm) will evaluate the applications for scientific and technical merit and responsiveness to the PAR.

As part of the initial merit review, all applications will:

o Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score

o Receive a written critique

o Receive a second level review by the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

**REVIEW CRITERIA**

The goals of NIAMS for this Small Grant program are to attract promising new investigators to conduct research in the rheumatic, musculoskeletal, and skin disease, along with the NIH-wide goals of advancing our understanding of biological systems, improving the control of disease, and enhancing health. The R03 is a mechanism for supporting discrete, well-defined projects that can realistically be expected to be completed within three years and that require only a modest level of funding. Because the research plan is limited to 10 pages, a small grant application will not have the same level of detail or extensive discussion found in an R01 application. Accordingly, reviewers will evaluate the conceptual framework and general approach to the problem, placing less emphasis on methodological details and certain indicators traditionally used in evaluating the scientific merit of R01 applications (e.g., hypothesis driven design,

supportive preliminary data). In the written comments reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the application's overall score, weighting them as appropriate for each application.

o Significance
o Approach
o Innovation
o Investigator
o Environment

The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

**SIGNIFCANCE:** Does this study address an important problem? If the study is descriptive rather than hypothesis driven, are the importance of the data to be obtained and their potential value in generating the proposed research generate data to answer a specific problem or lead to a larger scale research project? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

**APPROACH:.** Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the investigator acknowledge potential problem areas and consider alternative tactics? Can the proposed research realistically be accomplished within the requested period of support? Is the proposed approach appropriate to the state of the science, the stage of the research project, and the scope of the work? Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or investigator generated data. Reviewers recognize that an individual with limited research experience is less likely to be able to prepare a research plan with the breadth and depth of that submitted by a more experienced investigator. All applications must include a fundamentally sound research plan, but reviewers will consider the applicant's prior research experience in judging the level of detail provided. Preliminary data are not required.

**INNOVATION:** Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies, or will the data to be collected provide descriptive information needed to develop a new direction or area of research?

**INVESTIGATOR:** Based on the quality of the research and academic record, does he/she show potential to translate previous knowledge, skills, and research experience to areas of interest to NIAMS, and potential to make significant contributions to the field? Is

the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

**ENVIRONMENT:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following:

**PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK:** The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. (See criteria included in the section on Federal Citations, below).http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

**INCLUSION OF WOMEN, MINORITIES AND CHILDREN IN RESEARCH:** The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria in the sections on Federal Citations, below).

**CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH:** If vertebrate animals are to be used in the project, the five items described under Section f of the PHS 398 research grant application instructions (rev. 5/2001) will be assessed.

**ADDITIONAL CONSIDERATIONS**

**BUDGET:** The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

**AWARD CRITERIA**

Award criteria that will be used to make award decisions include:

- Scientific merit as determined by peer review
- Availability of funds
- Programmatic priorities
- Candidate's potential as an independent investigator

**REQUIRED FEDERAL CITATIONS**

**HUMAN SUBJECTS PROTECTION:** Federal regulations (45CFR46) require that

applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

**DATA AND SAFETY MONITORING PLAN:** Data and safety monitoring is required for all types of clinical trials, including physiologic, toxicity, and dose-finding studies (phase I); efficacy studies (phase II); efficacy, effectiveness and comparative trials (phase III). The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risk to the participants. (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

**INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH:** It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

**INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS:**
The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving

human subjects that is available at
http://grants.nih.gov/grants/funding/children/children.htm.

**REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS:** NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

**HUMAN EMBRYONIC STEM CELLS (hESC):** Criteria for federal funding of research on hESCs can be found at http://stemcells.nih.gov/index.asp and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see http://escr.nih.gov). It is the responsibility of the applicant to provide, in the project description and elsewhere in the application as appropriate, the official NIH identifier(s)for the hESC line(s)to be used in the proposed research. Applications that do not provide this information will be returned without review.

**PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT:** The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

**STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION:** The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities") must do so

by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

**URLs IN NIH GRANT APPLICATIONS OR APPENDICES:** All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

**HEALTHY PEOPLE 2010:** The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

**AUTHORITY AND REGULATIONS:** This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy.htm

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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Department of Health
and Human Services

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